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Bosnia and Herzegovina

Agricultural Biotechnology Annual

2014 Update

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Report Highlights:
Bosnia and Herzegovina recently started adopting regulations that govern biotech products. The 2009 Law on Genetically Modified Organisms set up the framework to approve imports and field releases of GMOs, but it took more than three years for BiH's Council of Ministers to adopt the five implementing rulebooks regarding the specific procedures to import and market biotech products and the regulation outlining the process for approving biotech cultivation is still missing. BiH's anti-biotech border practices, which include random testing, can occasionally influence commercial imports. Knowledge about biotechnology is still very limited, even among scientists and agricultural officials. The policy makers and farmers' main concern is that the country's export markets will be threatened if GE production is allowed in the country. Report updated: July, 2014.

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Section I. Executive Summary: Bosnia and Herzegovina (BiH) imports around two-thirds of its overall food needs. Its principal trading partners are neighboring countries such as Croatia, Serbia, and European Union (EU) countries. Imports of U.S. agro-food products have been limited and mainly consist of bulk commodities and some intermediate products (animal/vegetable fats & oils, nuts and fruits). Although there has not been much trade between BiH and the United States, reservations towards U.S.-origin foods appear to have increased recently. Generally, these impressions seem to be tied to fears about GE foods, seeds, and feed.

BiH recently started adopting regulations that govern biotech products. The 2004 Food Law did not allow biotech products to be imported or marketed pending implementing regulations. However, these regulations were never drafted; instead a new Law on Genetically Modified Organisms (GMO) was adopted in 2009. The new Law was intended to bring BiH's legislation in line with the EU regulations and it technically permitted the licensed use of GE products. However, only recently were most of the bylaws completed to define the approval process. Until these procedures were approved, no GE products could be allowed officially into the country and, to date, no licenses have been issued and there are none pending.

Generally speaking, GE products are viewed as undesirable in BiH due to a lack of consumer knowledge and negative media stories from some EU countries. The more sophisticated consumers on the other hand, think that they do not have enough information to be for or against biotech products and believe they need more reliable sources of education. More information from credible sources could positively change consumer attitudes towards biotechnology, as currently the more knowledgeable consumers say they would eat biotech foods after proper testing and labeling, if given enough information to make an informed decision.

The anti-GE position of many EU Member States has influenced both regulators and consumers, but it is not the only reason for Bosnia's resistance. Both the government and farmers tend to think that organic production is an important economic segment of BiH's agriculture. In BiH, traditional agricultural production practices predominate and the use of agrochemicals/pesticides is generally lower than elsewhere in Europe. There are also few industrial polluters. Many agricultural policy makers believe the country's export markets, especially potential organic export markets, would be threatened if GE production were allowed. Recently BiH's anti-biotech position has influenced commercial imports of grains as well. Although still infrequent, BiH randomly tests grain imports for GE content and has

rejected soybean meal from Brazil because it was GE and did not comply with the import requirements.

Section II. Author Defined:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: BiH does not produce biotech crops and there are no biotech crops under development in BiH.

b) COMMERCIAL PRODUCTION: There is no commercial production of GE plants in BiH.

c) EXPORTS: BiH does not export GE plants or products thereof.

d) IMPORTS: BiH officially doesn't import biotech crops/products or planting seeds. GE products may be imported, following the passage of the new regulation, but they must first be approved by the Food Safety Agency. Even products with EU approved events must go through the BiH approval process. The Food Safety Office has yet to receive an application..

e) FOOD AID RECEPIENT COUNTRIES: BiH was a food aid recipient as part of the USDA monetization program from 1997 to 2003. During that period, some biotech products were rejected as undesirable. For example, in 2000, U.S. corn offered as donation under the food aid/monetization project was rejected because it had biotech content. Two years later, the country accepted GE soybean meal imported from the U.S. as a donation only because it was approved for marketing in the EU.

PART B: POLICY

a) REGULATORY FRAMEWORK: The main laws that regulate agricultural biotechnology are the Food Law (BiH Official Gazette # 50/04) and the Law on Genetically Modified Organisms (BiH Official Gazette #23/09).

The Law on Genetically Modified Organisms is an overarching law for biotechnology. This Law sets the conditions for limited use, importation, deliberate release into environment, and marketing of products that are composed of GMOs, contain GMOs, or are derive from GMOs.

The Food Safety Agency (FSA) is the umbrella agency and coordinating body for all GMO issues. In addition to the FSA, other responsible agencies include the State Veterinary Office (SVO), the Plant Health Administration (PHA), and the entity-level and canton-level ministries of agriculture, health, and environment.

The FSA is responsible for placing biotech food and feed on the market. The PHA is responsible for approving biotech seeds and seedlings and plant protection chemicals, but first the entity and canton agricultural authorities and the Brcko District agricultural authorities must approve the product.

The SVO is responsible for approving veterinary medicines and genetic materials containing GMOs. The entity ministries of agriculture, health, and environment are responsible for regulating the contained use of GMOs or the deliberate release of GMOs into environment; however, they haven't started any activities on the regulation drafting.

The entity ministries of health and the Brcko District health department are responsible for approving cosmetics and pharmaceutical products containing GMOs. The entity and cantonal inspectorates and the Brcko District inspection department are responsible for checking proper labeling of GE products placed on the market.

The Law on GMOs sets general guidelines for the issuance of GMO permits. The following bylaws further regulate this area:

- The Bylaw on the Conditions and Procedure for Issuance of Approvals for Placing GMO Food and Feed on the BiH Market for the First Time and the Conditions Regarding their Traceability and Labeling
- The Bylaw on the Content of the Application and the Technical Documentation for Placing on the Market, and the Conditions for Labeling and Packaging of GMOs or Products that Contain or are Derive from GMOs
- The Bylaw on the Methods for Maintenance of a Common Register for GMOs
- The Bylaw on the Establishment of a System for the Development and Assignment of Unique Codes for GMOs
- The Bylaw on the Content and Scope of the Risk Assessment for Placing GMOs or Products that Contain or are Derive from GMOs on the Market and the Methodology for a Risk Assessment.

The above-mentioned bylaws, or rulebooks, are harmonized with EU biotech regulations and directives.

The FSA will process all permits in cooperation with the GMO Council and other responsible institutions. A risk assessment will be required with the request for a permit to import or place a GE food or feed product on the BiH market. Issuance of permits can take from 90-105 days, according to the Law on GMOs.

The Law on GMOs established a GMO Council to assist the responsible BiH institutions with enforcement. The GMO Council is a public independent body with a four-year mandate consisting of 7 members from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacology, biotechnology, agriculture, forestry, veterinary medicine, environmental protection, and occupational protection. The main tasks of the GMO Council are to advise on biotech usage in terms of legal procedures as outlined by the Law on GMOs, to give opinions and proposals on draft legislation on GMO use, to provide opinions and proposals to responsible ministries on biotech use issues and other expert work as outlined by the Law on GMOs and related regulations, to follow gene technology developments and use, to follow scientific progress in this area, to advise on social, ethical, technical, scientific and other conditions for GMO use, and to inform the public using media and professional fora on the status of gene technology developments and use. The GMO Council publically reports annually to the FSA and also to the Council of Ministers.

b) APPROVALS: No GE plants or plant products have been approved for import or cultivation yet.

c) FIELD TESTING: Currently there are no field tests of GE plants being conducted. The 2009 GMO Law established the general guidelines to allow for the intentional release of biotech products into the environment and field trials, under license, but the detailed regulations on licensing are still missing. The University of Sarajevo/Faculty of Agriculture and Food Sciences (FAFS) has begun the process of seeking permission to conduct field trials of a genetically engineered plum (the 'HoneySweet') which is resistant to the plum pox virus.

d) STACKED EVENTS APPROVAL: BiH's existing regulations do not have any special provisions to deal with stacked events. The GMO Council has yet to discuss how these will be handled in the future.

e) ADDITIONAL REQUIREMENTS: Seeds can be imported only if the varieties are recognized in the country. The National List of Recognized Varieties (BiH OG #59/10) is available at the Plant Health Administration. If a variety is not on the list, importers can request its recognition from the Seeds Commission (request forms available at the Ministries of Agriculture, per the Law on recognition of agricultural varieties Federation BiH Official Gazette 31/00 and the Law on Plant Protection RS Official Gazette 13/97).

f) COEXISTANCE: Regarding the coexistence between biotech and non-biotech crops, the Law on GMO forbids planting of biotechnology crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, and in protected areas (i.e. as defined as registered protected impact zones). In addition, biotech crop planting for reproduction is allowed only in areas that are approved by the Council of Ministers based on FSA's recommendations. In cases where the Law on GMOs cannot be applied, the Food Law and the bylaws derived from that law will apply.

g) LABELING: The Law on GMOs says that food products that contain or are composed of GMOs must be labeled as follows:

- For packaged products the label on the packaging should read: "This product contains GMO components" or "This product contains GM (name of organism)."
- For products that are not packaged the label should read "This product contains GMO components" or "This product contains GM (name of organism)" and should be placed directly on the product or by the product.

The labeling threshold is set at 0.9%, meaning that products containing approved biotech events at levels above 0.9% of the product must be labeled.

The Law on Seeds and Seedlings (BiH Official Gazette # 3/05) mentions only that biotech seeds and seedlings must be labeled.

h) TRADE BARRIERS: No additional information.

i) INTELECTUAL PROPERY RIGHTS (IPR): The Law on Industrial Property Rights (BiH Official

Gazette No. 3/02) and the Law on Copyrights (BiH Official Gazette 7/02) protect trademarks and brand names. Domestic and foreign applications must be submitted to the BiH Institute for Intellectual Property. According to research done by the U.S. Foreign Commercial Service, intellectual property rights (IPR) are often inadequately enforced and intellectual property, patents, copyrights and trademarks inadequately protected. BiH adopted and put into force a new IPR framework that consists of seven laws in 2010. This new legislation is compliant with the Agreement on Trade-Related Aspects of IPR (TRIPS) and EU regulations and includes laws on copyrights, patents, trademarks, geographical indications, and the topography of integrated circuits. Although existing legislation provides a basic level of protection, stronger enforcement is sought. Jurisdiction over IPR investigations is split between customs officials, entity inspectorates, and state and entity law enforcement agencies, and no institution has specialized IPR investigation teams. IPR crimes are prosecuted primarily at the State level.

j) CARTAGENA PROTOCOL RATIFICATION: BiH is party to the Cartagena Biosafety Protocol. It was ratified on October 1, 2009, and it entered into force on December 31, 2009. The country's necessary legal, administrative and other measures for the implementation of the Protocol are partially in place, and a mechanism for budgetary allocations for operating its national biosafety framework is missing. Detection and identification of living modified
organisms is done to some extent, but there is a lack of proper risk assessment and risk management, as well as information exchange and data management. There is no mechanism addressing emergency measures in case of unintentional trans-boundary movements, and public awareness and education on biosafety are missing.

k) INTERNATIONAL TREATIES/FORA: The country doesn't actively participate in discussions related to GE plants within the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex).

l) RELATED ISSUES: No additional information.

m) MONITORING AND TESTING: The following four laboratories have been authorized to do biotech testing:

- The Biotechnology Laboratory of the Agricultural Institute in Banja Luka;
- The GMO Laboratory of the Federation Agro-Mediterranean Institute in Mostar;
- The Laboratory for GMOs and Food of the Institute for Genetic Engineering and Biotechnology in Sarajevo;
- The GMO Laboratory of the Federation Agricultural Institute in Sarajevo.

During the last year the Sarajevo and Banja Luka Agricultural Institutes have received GMO testing equipment worth $0.3 million through a World Bank loan. Using this new equipment, the laboratories will be able to use Real-Time Polymerase Chain Reaction (PCR) technology to detect not only the presence of biotech events (as before), but also the amount of the biotech event present in the food and feed samples. The labs will be able to conduct an event-specific detection to identify the biotech event. However, there currently is no need for this testing as there are no approved biotech events in BiH yet. The Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana in Italy currently is the designated reference laboratory to do biotech testing, because none of BiH's domestic laboratories have

that capacity yet.

The country currently only conducts random testing of GE products, but in the beginning of 2013 it started drafting a national GMO monitoring plan per the draft Regulation on Conditions of Monitoring the Environmental Impact of GMOs, Products Containing and/or Consisting of GMOs or Derived from GMOs and their Use. The monitoring plan will cover monitoring and surveillance of GMOs, contained use of GMOs, procedures relating to the deliberate release of GMOs into the environment, placing on the market of GMOs and products containing and/or consisting of or originating from GMOs, and possible adverse effects, pursuant to the Law on GMOs and other regulations. The Food Safety Office hasn't made available the findings of the 2013 GMO monitoring plan yet.

n) LOW LEVEL PRESENCE POLICY: BiH has no Low Level Presence (LLP) policy. The GMO Council has stated that BiH's regulation is currently harmonized with the EU regulation and that BiH will keep following the EU guidelines on this subject in the future.

PART C: MARKETING

a) MARKET ACCEPTANCE: The market acceptance of biotech products for producers, importers, retailers, and consumers is officially unknown.

b) PUBLIC/PRIVATE OPINIONS: Knowledge about biotechnology is poor even among scientists and agricultural officials. The recent war in BiH caused a wide range of destruction, and the country still suffers from a poor economic situation. As a result, biotechnology is still a relatively new issue. Overall, the level of biotech acceptance has decreased during the last five years due to EU attitudes and the anti-biotech views of neighboring countries, such as Croatia and Serbia. Also, agriculturists and non-governmental organizations that promote organic agriculture have been vocal opponents and have influenced producers, consumers, and regulators to reject biotech products. Occasionally, the media and consumer associations in BiH criticize BiH authorities for not having better controls of imported foods with biotech content and for approving the import of biotech commodities.

c) MARKETING STUDIES: There have been no studies regarding this topic.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: There were four outreach activities carried out in BiH over the past two years that relate to plant biotechnology.

In September/October 2012 the US Embassy-Sarajevo arranged along with some local partners a roundtable for key BiH officials at both the entity and state-level. An EU and a United States expert were invited. Mr. Felix Nicolescu, the Principal Councilor at the Romanian Food Safety Authority and representative on the EU's Standing Committee on Food Chain and Animal Health, talked about the European Union authorization process. Dr. Ralph Scorza, USDA/ARS scientist for genetic improvement of fruit, talked about a GE plum, which is resistant to the plum-pox virus (a plant disease seriously affecting BiH's plum orchards). The GE disease-resistant plum was used as an example of how GMOs can be an effective agricultural production tool and how biotechnology approvals and use

can be carried-out within the framework of the EU's laws.

In June 2013, the US Embassy-Sarajevo worked with local partners to organize a technical workshop for the livestock sector. The North American Export Grain Association (NAEGA) sponsored a speaker from its European counterpart (COCERAL) and two local experts discuss the benefits of modern technology and good agricultural practices in preventing aflatoxin problems and improving trade prospects. The two events underlined the need for BiH's institutions to adopt internationally recognized transparent science-based standards to ensure BiH's livestock producers have access to safe and affordable feed and BiH's exports are wholesome.

In September 2013, the US Embassy-Sarajevo worked with the Food Safety Agency to organize a technical workshop for importers and policymakers. The guest speakers were Dr. Gonzalo Mateos, Professor of Animal Nutrition at the Polytechnic University of Madrid, Spain; Mr. Felix Nicolescu of the National Sanitary Veterinary and Food Safety Authority in the Government of Romania; and BiH Food Safety Agency Deputy Director Zoran Djeric. During the two sessions in Sarajevo and Banja Luka the speakers presented procedures for placing biotechnology feed on the market, discussed the nutritional value, economic impact, and future trends of biotechnology products, such as soybeans and corn.

In April 2014, U.S. Embassy Sarajevo in cooperation with USAID's agricultural project FARMA and the University of Sarajevo, Faculty of Agriculture and Food Sciences (FAFS) conducted a series of biotech outreach activities. The program was designed for BiH's regulatory authorities and small and medium-sized farmers to discuss a possible field trial for a biotech plum ("HoneySweet"). Romanian researcher, Dr. Ioan Zagrai, who is currently testing the "HoneySweet" plum at Romania's Fruit Research Station in Bistrita and Dr. Fuad Gasi, FAFS' led the discussions on the proposed BiH field trials. Dr. Zagrai also took the opportunity to outline for FAFS the EU government approval process and to discuss the technical details surrounding the launch of a biotech field trial for this type of product. Dr. Zagrai also met with the Council for Genetically Modified Organisms (GMO) to discuss the procedure for approving such a field trial.

b) STRATEGIES AND NEEDS: As BiH is still in the process of creating its regulatory structure for approving biotech products, future informational events regarding scientific and productive evidence from the United States could have a positive impact. Possible topics would include the approval procedures for placing GE products on the market and the development of science-based requirements for the field trial application process.

CHAPTER 2: ANIMAL BIOTECHNOLOGY:

PART E: PRODUCTION AND TRADE

a. BIOTECHNOLOGY PRODUCT DEVELOPMENT: Genetic engineering and cloning are not being developed in BiH for the production of agricultural animals.

b. COMMERCIAL PRODUCTION: The livestock sector in BIH is not actively employing the use of genetically engineered animals or products derived from genetically engineered animals or clones.

c. BIOTECHNOLOGY EXPORT/IMPORTS: BiH neither exports nor imports GE animals, livestock clones, or products from these animals, although it is unknown whether any imported genetic material was produced with modern biotechnology techniques or originated from clones or from the off-spring of clones.

PART F: POLICY

a) REGULATION: BiH has no laws or regulations relating to the development, commercial use, import, and/or disposal of GE animals and clones, or products derived from these animals, and currently there are no plans to draft such regulations.

The relevant government entities that likely would have a role in the regulation of GE animals are the State Veterinary Office and the Food Safety Agency, but to date there have been no active discussions about these products or by-products nor were they mentioned in the new GMO Law. As BiH's is harmonizing its regulation with the EU regulation, the country will keep following the EU guidelines on this subject in the future.

b) LABELING AND TRACEABILTY: There is no policy on labeling and traceability of GE animals and clones.

c) TRADE BARRIERS: No additional information.

d) INTELECTUAL PROPERTY RIGHTS (IPR): The country is not considering legislation to address IPR for animal biotechnologies.

e) INTERNATIONAL TREATIES/FORA: The country doesn't actively participate in discussions related to GE animals and clones within the Codex Alimentarius (Codex) and the World Animal Health Organization.

PART G: MARKETING

a) MARKET ACCEPTANCE: There is only very little awareness of GE animals or cloning in BiH. The market acceptance of GE animals and clones for producers, importers, retailers, and consumers is unknown.

b) PUBLIC/PRIVATE OPINIONS:
There have been no public campaigns and almost no media reports on this topic in BiH. It can be expected that the acceptance of GE animals and clones is negative.

c) MARKET STUDIES: There are no specific marketing studies regarding GE animals and/or cloning use or acceptance.

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: There have been no outreach activities on GE animals or cloning so far.

b) STRATEGIES AND NEEDS: It might be useful to support in-country informational events involving U.S. scientific and/or agricultural production authorities to speak to the relevant BiH stakeholders and lead discussions on this topic between BiH authorities and the scientific community. A recommended topic would be development of science-based regulation on GE animals and clones.